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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,800	01/17/2006	William Levine	4110-42	4537

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,800	LEVINE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on March 12, 2008 has been received and entered. Currently, Claims 1-3, 5-16 are pending. Claims 1-3, 5-16 are examined on the merits. Claim 4 is canceled.

Election/Restrictions

Applicant's election without traverse of Sambucus nigra, Centella asiatica, Enchinacea purpurea in the reply filed on Dec. 15, 2006 is acknowledged.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289) and Grinstaff et al. (US 5639473).

Oppenheim et al. teaches herbal extract solutions suitable for encapsulation in a soft gelatin capsule or tablet mixed with solid excipient materials (page 1, lines 3-4, 19, 26-37) and Centella asiatica (page 6, line 29), Echinacea purpurea (page 7, line 7-8), Sambucus nigra (page 8, line 23). However, it does not teach polymer of acrylic acid and polyvinylpyrrolidone, mucosal tissue.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell, where in vivo delivery is oral (buccal), suppository (rectal or anal), pessary (vaginal) (column 8, lines 15-20), polymeric shell can be formed from polyacrylic acid and polyvinyl pyrrolidinone (column 9, lines 11-17). The non-adhesive side would be intrinsically taught because the inside of the shell would be in contact with the dispersing agent; thus, the dispersing agent would be the non-adhesive side.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell. Oppenheim et al. teaches herbal extract solutions suitable for encapsulation. Thus, an artisan of ordinary skill would reasonably expect that polymeric shell could be used as the types of encapsulation taught by the references. This reasonable expectation of success would motivate the artisan to use polymeric shell in the reference composition. Thus, using polymeric shell is considered an obvious modification of the references.

Claims 1-2, 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289) and Grinstaff et al. (US 5639473) as applied to claims 1-2, 8-10 above, and further in view of Brinkhaus et al. (2000, Phytomedicine, 7, pages 427-448).

Oppenheim et al. teaches herbal extract solutions suitable for encapsulation in a soft gelatin capsule or tablet mixed with solid excipient materials (page 1, lines 3-4, 19, 26-37) and Centella asiatica (page 6, line 29), Echinacea purpurea (page 7, line 7-8), Sambucus nigra (page 8, line 23). However, it does not teach polymer of acrylic acid and polyvinylpyrrolidone, mucosal tissue lesion.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell, where in vivo delivery is oral (buccal), suppository (rectal or anal), pessary (vaginal) (column 8, lines 15-20), polymeric shell can be formed from polyacrylic acid and polyvinyl pyrrolidinone (column 9, lines 11-17). The non-adhesive side would be intrinsically taught because the inside of the shell would be in contact with the dispersing agent; thus, the dispersing agent would be the non-adhesive side.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell. Oppenheim et al. teaches herbal extract solutions suitable for encapsulation. Thus, an artisan of ordinary skill would reasonably expect that polymeric shell could be used as the types of encapsulation taught by the references. This reasonable expectation of success would motivate the artisan to use

polymeric shell in the reference composition. Thus, using polymeric shell is considered an obvious modification of the references.

Brinkhaus et al. teaches Centella extract is associated with acceleration of healing of lesions after administration in gastrointestinal ulcers (mucosal lesion) (page 436, Ulcer-protective and anti-ulcer effects).

Locally delivered drug treatments to the sight of the mucosal lesion would increase the dose and expose to the drug for the lesion. Thus, it would be obvious to apply the drugs to the sight of lesion, such as that taught by Brinkhaus et al. An artisan of ordinary skill would clearly expect that the lesion treatment taught by Brinkhaus et al. would function successfully to administer the herbal extracts taught by Oppenheim et al. This reasonable expectation of success would motivate the artisan to modify mucosal treatment with herbal extracts to include localized lesion treatment as an effective means to administer the herbal extracts.

Claims 1-3, 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289), Grinstaff et al. (US 5639473), Brinkhaus et al. (2000, Phytomedicine, 7, pages 427-448) as applied to claims 1-2, 8-14 above, and further in view of Kim et al. (US 2002/0165169 A1).

Oppenheim et al. teaches herbal extract solutions suitable for encapsulation in a soft gelatin capsule or tablet mixed with solid excipient materials (page 1, lines 3-4, 19, 26-37) and Centella asiatica (page 6, line 29), Echinacea purpurea (page 7, line 7-8), Sambucus nigra (page 8, line 23). However, it does not teach polymer of acrylic acid

and polyvinylpyrrolidone, mucosal tissue lesion, hydroxypropyl cellulose, lactose, concentrations.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell, where in vivo delivery is oral (buccal), suppository (rectal or anal), pessary (vaginal) (column 8, lines 15-20), polymeric shell can be formed from polyacrylic acid and polyvinyl pyrrolidinone (column 9, lines 11-17). The non-adhesive side would be intrinsically taught because the inside of the shell would be in contact with the dispersing agent; thus, the dispersing agent would be the non-adhesive side.

Brinkhaus et al. teaches Centella extract is associated with acceleration of healing of lesions after administration in gastrointestinal ulcers (mucosal lesion) (page 436, Ulcer-protective and anti-ulcer effects).

Locally delivered drug treatments to the sight of the mucosal lesion would increase the dose and expose to the drug for the lesion. Thus, it would be obvious to apply the drugs to the sight of lesion, such as that taught by Brinkhaus et al. An artisan of ordinary skill would clearly expect that the lesion treatment taught by Brinkhaus et al. would function successfully to administer the herbal extracts taught by Oppenheim et al. This reasonable expectation of success would motivate the artisan to modify mucosal treatment with herbal extracts to include localized lesion treatment as an effective means to administer the herbal extracts.

Kim et al. teaches pharmaceutically acceptable excipients such as hydroxypropyl cellulose, diluting agents with lactose to prepare pharmaceutical formulations for oral,

parenteral administration such as tablets, capsules, soft capsules, liquids, ointmantes, pills, suspensions, emulsions, syrups, suppositories (paragraph 0025).

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell. Oppenheim et al. teaches herbal extract solutions suitable for encapsulation. Kim et al. teaches pharmaceutically acceptable excipients such as hydroxypropyl cellulose, diluting agents with lactose (see discussion above). Thus, an artisan of ordinary skill would reasonably expect that polymeric shell could be used as the types of encapsulation, where the excipient can include hydroxypropyl cellulose and the herbal extract can be diluted with lactose, taught by the references. This reasonable expectation of success would motivate the artisan to use polymeric shell and excipients and diluents in the reference composition. Thus, using polymeric shell and excipients and diluents is considered an obvious modification of the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in

order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-3, 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289), Grinstaff et al. (US 5639473), Brinkhaus et al. (2000, Phytomedicine, 7, pages 427-448), and Kim et al. (US 2002/0165169 A1) as applied to claims 1-3, 5-15 above, and further in view of Britton et al. (US 5863553).

Oppenheim et al. teaches herbal extract solutions suitable for encapsulation in a soft gelatin capsule or tablet mixed with solid excipient materials (page 1, lines 3-4, 19, 26-37) and Centella asiatica (page 6, line 29), Echinacea purpurea (page 7, line 7-8), Sambucus nigra (page 8, line 23). However, it does not teach polymer of acrylic acid and polyvinylpyrrolidone, mucosal tissue, hydroxypropyl cellulose, lactose, concentrations, and contacting for a period of time ranging about 1 hours to about 5 hours.

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell, where in vivo delivery is oral (buccal), suppository (rectal or anal), pessary (vaginal) (column 8, lines 15-20), polymeric shell can be formed from polyacrylic acid and polyvinyl pyrrolidinone (column 9, lines 11-17). The non-adhesive side would be intrinsically taught because the inside of the shell would be in contact with the dispersing agent; thus, the dispersing agent would be the non-adhesive side.

Brinkhaus et al. teaches Centella extract is associated with acceleration of healing of lesions after administration in gastrointestinal ulcers (mucosal lesion) (page 436, Ulcer-protective and anti-ulcer effects).

Locally delivered drug treatments to the sight of the mucosal lesion would increase the dose and expose to the drug for the lesion. Thus, it would be obvious to apply the drugs to the sight of lesion, such as that taught by Brinkhaus et al. An artisan of ordinary skill would clearly expect that the lesion treatment taught by Brinkhaus et al. would function successfully to administer the herbal extracts taught by Oppenheim et al. This reasonable expectation of success would motivate the artisan to modify mucosal treatment with herbal extracts to include localized lesion treatment as an effective means to administer the herbal extracts.

Kim et al. teaches pharmaceutically acceptable excipients such as hydroxypropyl cellulose, diluting agents with lactose to prepare pharmaceutical formulations for oral, parenteral administration such as tablets, capsules, soft capsules, liquids, ointmantes, pills, suspensions, emulsions, syrups, suppositories (paragraph 0025).

Grinstaff et al. teaches compositions for in vivo delivery of biocompatiable dispersing agent with polymeric shell. Oppenheim et al. teaches herbal extract solutions suitable for encapsulation. Kim et al. teaches pharmaceutically acceptable excipients such as hydroxypropyl cellulose, diluting agents with lactose (see discussion above). Thus, an artisan of ordinary skill would reasonably expect that polymeric shell could be used as the types of encapsulation, where the excipient can include hydroxypropyl cellulose and the herbal extract can be diluted with lactose, taught by the

references. This reasonable expectation of success would motivate the artisan to use polymeric shell and excipients and diluents in the reference composition. Thus, using polymeric shell and excipients and diluents is considered an obvious modification of the references.

Britton et al. teaches suppository having a dissolution time of at least about 2 hours and up to about 24 hours (Abstract).

The references also do not specifically teach dissolution in the time span range claimed by applicant. The dissolution in the time span range is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the time span and temperature range to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references do not specifically teach using the composition to treat mucosal tissue. However, the method of oral, vaginal, and anal application is considered to intrinsically teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is

the same because every person has mucosal tissue. Thus, on the administration of the composition by oral, vaginal and anal applications to any patient, a treatment of mucosal tissue would have had to occur if applicant's invention function as claimed.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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